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Attorneys for Plaintiff Ferring Pharmaceuticals Inc.

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

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FERRING PHARMACEUTICALS INC.,  
  
Plaintiff,

v.

WATSON PHARMACEUTICALS, INC.,  
  
Defendant.

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:  
: Civil Action No.:  
: 2:12-cv-05824-DMC-JAD  
:  
: ELECTRONICALLY FILED  
:  
: **DECLARATION OF BRIAN R.**  
: **MICHALEK IN SUPPORT OF**  
: **PLAINTIFF'S MOTION FOR A**  
: **PRELIMINARY INJUNCTION**  
:  
:

I, Brian R. Michalek, declare as follows:

1. I am an attorney in the law firm of Olson & Cepuritis, Ltd., 20 N. Wacker Drive, 36<sup>th</sup> floor, Chicago, Illinois 60606, attorneys (together with Norris, McLaughlin & Marcus, P.A.) for Plaintiff Ferring Pharmaceuticals Inc. ("Ferring"). I submit this declaration in support of Ferring's Motion for a

Preliminary Injunction. All of the facts set forth herein are known to me personally, and if called as a witness, I could and would testify competently thereto.

2. Exhibit 1 attached hereto is a true copy of excerpts from a Watson Crinone brochure.

3. Exhibit 2 attached hereto is a true copy of the Internet webpage <http://www.ferringfertility.com/endometrin> accessed on November 8, 2012.

4. Exhibit 3 attached hereto is a true copy of the Internet webpage [http://www.crinoneusa.com/patient/role of progesterone in pregnancy.asp](http://www.crinoneusa.com/patient/role_of_progesterone_in_pregnancy.asp) accessed on November 7, 2012.

5. Exhibit 5 attached hereto is a true copy of transcript excerpts from Dr. Kaylen M. Silverberg's September 11, 2012, 7:30 PM Webcast presentation.

6. Exhibit 6 attached hereto is a true copy of Endometrin's packaging insert bearing bates numbers WATSON00853-54.

7. Exhibit 7 attached hereto is a true copy of transcript excerpts from Dr. Kaylen M. Silverberg's September 11, 2012, 9:00 PM Webcast presentation.

8. Exhibit 11 attached hereto is a true copy of an FDA Warning Letter.

9. Exhibit 12 attached hereto is a true copy of an article authored by William Schoolcraft, et al. and bearing bates number WATSON00902.

10. Exhibit 13 attached hereto is a true copy of an article authored by Kevin J. Doody, et al. and bearing bates number WATSON00847-52.

11. Exhibit 14 attached hereto is a true copy of a screenshot capture of Google search engine search for Endometrin.

12. Exhibit 15 attached hereto is a true copy of excerpts from a treatise entitled McCarthy on Trademarks, 4<sup>th</sup> Edition.

13. Exhibit 16 attached hereto is a true copy of excerpts from a treatise entitled "FDA Advertising and Promotion."

I hereby declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: November 9, 2012  
Chicago, IL



Brian R. Michalek

# Exhibit 1



# Supporting a healthy pregnancy

The role of progesterone  
in Assisted Reproductive  
Technology (ART)

Crinone<sup>®</sup>  
progesterone gel 8%

## Progesterone and its role in pregnancy

### Progesterone

Progesterone is a hormone produced by the ovaries and, later, if pregnancy occurs, by the placenta. Progesterone is essential to achieve and maintain a healthy pregnancy. In the second half of a woman's menstrual cycle, progesterone prepares the endometrium, or uterine lining, to receive the fertilized egg. If implantation is successful and pregnancy occurs, progesterone continues to support the uterine lining, providing the perfect environment for the growing embryo.

Progesterone plays 2 important roles:

1. Progesterone thickens and prepares the lining of the uterus for implantation of a fertilized egg.
2. After implantation, progesterone is required to maintain pregnancy.

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### Progesterone therapy in ART

If IVF or other ART treatments are recommended, fertility medications almost always essential to the process. Certain medications and typically used in the initial phase of ART can interfere with natural production; therefore, it is necessary to supplement, or in some cases, progesterone to ensure that the embryo is fully supported by the

Depending on the type of ART procedure recommended, your doctor will determine the amount of progesterone that is right for you and you should take it to maximize your chance for a successful pregnancy.



## Pregnancy support with CRINONE

In the early days of ART, progesterone had to be administered by intramuscular injection. Fortunately, this is no longer the case. Advanced pharmaceutical research has developed CRINONE gel—a natural vaginal progesterone. Women have been enjoying the benefits and ease of vaginal progesterone for more than 10 years with CRINONE gel. CRINONE is the only FDA-approved once-daily vaginal progesterone available today.

CRINONE vaginal gel offers a generally well-tolerated, effective, and convenient way of getting this vital medication. In addition, by inserting the gel vaginally, the progesterone is transported directly to the uterus, where it is needed most—without first traveling through your entire body, as is the case with injections.

CRINONE also provides a benefit because it is designed to adhere to the vaginal wall, so CRINONE can be administered just once a day. This provides you with the most convenient progesterone treatment when compared to vaginal suppositories, capsules, or inserts—which require dosing 2 or 3 times a day.

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CRINONE is a specially formulated once-daily gel containing natural progesterone. CRINONE is a unique bioadhesive gel that coats and adheres to the vaginal wall application. Progesterone is then absorbed into the vaginal wall directly to the uterus throughout the day, providing effective, continuous support. What's more, CRINONE is generally well tolerated, comfortable.



Crinone<sup>®</sup>  
progesterone gel 8%

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# **Exhibit 2**





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Patient Contest

Bravelle®  
(urofollitropin for injection purified)

Menopur®  
(menotropins for injection USP)

Endometrin®  
(progesterone) Vaginal Insert 100mg

Repronex®  
(menotropins for injection USP)

Novarel®  
(chorionic gonadotropin for injection USP)

**Endometrin®**  
(progesterone) Vaginal Insert 100mg

supporting your pregnancy  
with ENDOMETRIN®

ABOUT ENDOMETRIN

HOW TO USE

ADMINISTRATION

FAQs

Download ENDOMETRIN  
Prescribing Information



ENDOMETRIN is a vaginal insert containing 100 mg of micronized progesterone. Progesterone is a natural hormone that is often used to help your uterine lining receive and nourish a fertilized egg. While several forms of progesterone are available, only 2 are FDA-approved for luteal support. In a US IVF trial with over 1200 patients, ENDOMETRIN was clinically proven to help achieve high pregnancy and birth rates.

Each ENDOMETRIN insert comes with its own single-use disposable applicator for sterile administration. Once you've administered the insert, simply discard the applicator. Typical dosing is 2 or 3 times a day as prescribed by your doctor.

Find a Pharmacy [GO](#)

Find a Physician [GO](#)

Injection Training [GO](#)

#### **BRAVELLE® (urofollitropin for injection, purified)**

BRAVELLE® (urofollitropin for injection, purified) is a prescription medicine that contains hormones. BRAVELLE contains follicle stimulating hormone which stimulates healthy ovaries to make eggs. BRAVELLE is used for women who need medical help to get pregnant. Your doctor may prescribe more than one medicine as part of a pregnancy plan.

#### **Important Safety Information**

Do not use BRAVELLE if you: have ovaries that are not able to make eggs even with the use of hormones, are pregnant or think you may be pregnant, have problems with your thyroid gland or adrenal gland that are not controlled by taking medicine, have cancer in your female organs (ovaries, breasts, uterus), have a tumor of your pituitary gland or any other tumor in your brain, or have heavy or irregular vaginal bleeding and the cause is not known.

BRAVELLE may cause serious side effects. It sometimes stimulates the ovaries too much. This is called ovarian hyperstimulation syndrome (OHSS) and can be a serious medical problem. OHSS may cause pelvic pain or breathing problems, or it may make you urinate less. In rare cases, patients with this problem have had serious lung problems. BRAVELLE can also cause blood clots and strokes. Call your doctor or get medical help right away if you have: severe pelvic pain, nausea, vomiting, diarrhea, sudden weight gain, trouble breathing, or decreased or no urination. BRAVELLE may cause you to be pregnant with twins or more than two babies at the same time.

The most common side effects with BRAVELLE are stomach cramps and headache.

Please see full [Prescribing Information](#) for BRAVELLE.

#### **MENOPUR® (menotropins for injection, USP)**

MENOPUR® (menotropins for injection, USP) is a prescription medicine that contains hormones. MENOPUR contains the hormones follicle stimulating hormone and luteinizing hormone. These hormones stimulate healthy ovaries to make eggs. MENOPUR is used for women who need medical help to get pregnant. Your doctor may prescribe more than one medicine as part of a pregnancy plan.

#### **Important Safety Information**

Do not use MENOPUR if you: have ovaries that are not able to make eggs even with the use of hormones, are pregnant or think you may be pregnant, have problems with your thyroid gland or adrenal gland that are not controlled by taking medicine, have cancer in your female organs

(ovaries, breasts, uterus), have a tumor of your pituitary gland or any other tumor in your brain, or have heavy or irregular vaginal bleeding and the cause is not known.

MENOPUR may cause serious side effects. It sometimes stimulates the ovaries too much. This is called ovarian hyperstimulation syndrome (OHSS) and can be a serious medical problem. OHSS may cause pelvic pain or breathing problems, or it may make you urinate less. In rare cases, patients with this problem have had serious lung problems. MENOPUR can also cause blood clots and strokes. Call your doctor or get medical help right away if you have: severe pelvic pain, nausea, vomiting, diarrhea, sudden weight gain, trouble breathing, or decreased or no urination. MENOPUR may cause you to be pregnant with twins or more than two babies at the same time.

The most common side effects with MENOPUR are headache, stomach pain, and upset stomach. Sometimes there is an injection-site reaction that can cause bruising, pain, or redness.

Please see full [Prescribing Information](#) for MENOPUR.

### **ENDOMETRIN® (progesterone)**

ENDOMETRIN® (progesterone) is a vaginal insert that contains the hormone progesterone, one of the hormones essential for helping you to become and to stay pregnant. ENDOMETRIN is for women who need extra progesterone while undergoing treatment in an Assisted Reproductive Technology (ART) program.

### **Important Safety Information**

Do not use ENDOMETRIN if you:

- Are allergic to anything in ENDOMETRIN
- Have unusual vaginal bleeding that has not been evaluated by a doctor
- Currently have or have had liver problems
- Have or have had blood clots in the legs, lung, eyes, or elsewhere in your body

Progesterone can increase your chance of getting blood clots. Blood clots can be serious and lead to death. Serious blood clots include those in the legs, lungs, eyes, heart, and brain.

Call your doctor and get medical help right away if you have: persistent lower leg pain, sudden shortness of breath, coughing up blood, sudden blindness (partial or complete), severe chest pain, sudden severe headache, vomiting, dizziness, or fainting, weakness in an arm or leg, or trouble speaking, yellowing of the skin and/or white of the eyes indicating possible liver problems.

Common side effects seen with ART and ENDOMETRIN included pelvic pain after surgery, abdominal pain, nausea, and swollen ovaries (ovarian hyperstimulation syndrome).

Please see full [Prescribing Information](#) for ENDOMETRIN.

### **REPRONEX® (menotropins for injection, USP)**

REPRONEX® (menotropins for injection, USP) is a prescription medicine that contains purified hormones. REPRONEX contains the hormones follicle stimulating hormone and luteinizing hormone. These hormones stimulate healthy ovaries to make eggs. REPRONEX is used for women who need medical help to get pregnant. Your doctor may prescribe more than one medicine as part of a pregnancy plan.

### **Important Safety Information**

Do not use REPRONEX if you: have ovaries that are not able to make eggs even with the use of hormones, are pregnant or think you may be pregnant, have problems with your thyroid gland or adrenal gland that are not controlled by taking medicine, have cancer in your female organs (ovaries, breasts, uterus), have a tumor of your pituitary gland or any other tumor in your brain, or have heavy or irregular vaginal bleeding and the cause is not known.

REPRONEX may cause serious side effects. It sometimes stimulates the ovaries too much. This is called ovarian hyperstimulation syndrome (OHSS) and can be a serious medical problem. OHSS may cause pelvic pain or breathing problems, or it may make you urinate less. In rare cases, patients with this problem have had serious lung problems. REPRONEX can also cause blood clots and strokes. Call your doctor or get medical help right away if you have: severe pelvic pain, nausea, vomiting, diarrhea, sudden weight gain, trouble breathing, or decreased or no urination. REPRONEX may cause you to be pregnant with twins, or more than two babies at the same time.

The most common side effects with REPRONEX are headache, stomach pain, and upset stomach. Sometimes there is an injection-site reaction that can cause bruising, pain, or redness.

Please see full [Prescribing Information](#) for REPRONEX.

### **NOVAREL® (chorionic gonadotropin for injection, USP)**

NOVAREL® (chorionic gonadotropin for injection, USP) is a prescription medicine that contains a hormone to help stimulate healthy ovaries to make eggs. NOVAREL is used for women who need medical help to get pregnant. Your doctor may prescribe more than one medicine as part of a pregnancy plan.

### **Important Safety Information**

Do not use NOVAREL if you have begun puberty at an unusually early age, have prostate cancer, or have had a prior allergic reaction to this hormone. This hormone may cause harm to an unborn baby when given to a pregnant woman.

NOVAREL may cause serious side effects. It sometimes stimulates the ovaries too much. This is called ovarian hyperstimulation syndrome (OHSS) and can be a serious medical problem. OHSS may cause pelvic pain or breathing problems, or it may make you urinate less. In rare cases, patients with this problem have had serious lung problems. NOVAREL can also cause blood clots and strokes. Call your doctor or get medical help right away if you have: severe pelvic pain, nausea, vomiting, diarrhea, sudden weight gain, trouble breathing, or decreased or no urination. NOVAREL may cause you to be pregnant with twins or more than two babies at the same time.

Other side effects of NOVAREL include headache, irritability, restlessness, depression, fatigue, swelling, and pain at the site of injection.

Anaphylaxis has been reported with urinary-derived hCG products.

Please see full [Prescribing Information](#) for NOVAREL.


**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

All information on this site is intended for US audiences only.

BRAVELLE, MENOPUR, ENDOMETRIN, REPRONEX, and NOVAREL are registered trademarks of Ferring B.V.

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# **Exhibit 3**




Helping Dreams of Pregnancy Come True.

[Prescribing Information](#)
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[THE MENSTRUAL CYCLE](#)
[ROLE OF PROGESTERONE IN PREGNANCY](#)
[ABOUT CRINONE](#)
[FAQs](#)
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**CRINONE 8% Patient Brochure**



Supporting a healthy pregnancy

Download

**CRINONE 8% Patient Instruction Sheet**



Once-daily CRINONE 8% helps Progesterone Support Your Pregnancy

Download (English)

Download (Spanish)

## Progesterone is essential to achieving and maintaining a pregnancy

### Progesterone prepares the uterus for pregnancy

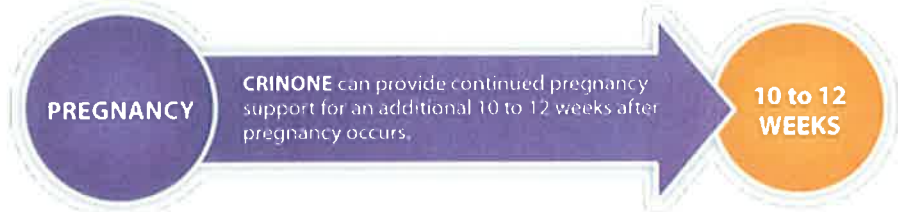
When you're trying to achieve pregnancy, your body needs progesterone to support the growth of an embryo. At the midpoint of the menstrual cycle, ovulation occurs when a mature egg is released. The now-empty ovarian follicle—called the corpus luteum—produces progesterone that prepares the lining of the uterus (endometrium) to receive and nourish an embryo.

### Progesterone supports the embryo

When an egg is fertilized by a sperm, the embryo travels down the fallopian tube to the uterus and attaches to the endometrium—a process called implantation. At this stage, progesterone from the corpus luteum is essential to supporting the embryo's growth. During pregnancy, the placenta begins to produce progesterone about 6 to 7 weeks after the egg is fertilized. By 10 to 12 weeks, the placenta is supplying an adequate amount of progesterone to maintain the pregnancy.

### Progesterone during Assisted Reproductive Technology (ART) treatment

If you are undergoing ART treatment and your doctor has determined that your body does not produce enough progesterone on its own, CRINONE may be prescribed to provide the progesterone you need. CRINONE contains the natural female hormone progesterone that will help prepare the lining of your uterus for an embryo. Once pregnancy occurs, CRINONE may be used for an additional 10 to 12 weeks for continued pregnancy support until the placenta is producing an adequate amount of progesterone.



**PREGNANCY**

CRINONE can provide continued pregnancy support for an additional 10 to 12 weeks after pregnancy occurs.

**10 to 12 WEEKS**

[LEARN HOW](#) CRINONE may help increase your chances of pregnancy.

**#1 Prescribed Vaginal Progesterone**

## Indication and Usage

CRINONE 8% (progesterone gel) is indicated for progesterone supplementation or replacement as part of an Assisted Reproductive Technology (ART) treatment for infertile women with progesterone deficiency.

## Important Safety Information

The most common side effects of CRINONE 8% (progesterone gel) include breast enlargement, constipation, drowsiness, nausea, headache, and pain in the pubic area. You should not use CRINONE 8% if you have any disorders involving blockage of your blood vessels, or a history of these disorders, miscarriages, vaginal bleeding that hasn't been diagnosed, liver problems or disease, or known or possible cancer of the breast or genital organs. You should discontinue use of CRINONE 8% if any symptoms occur that signal a blockage of your blood vessels. There is no evidence that CRINONE 8% will work in preventing miscarriage. Your doctor should examine your breasts and pelvic organs, as well as perform a Pap smear prior to prescribing CRINONE 8%. If you have vaginal bleeding during treatment with CRINONE 8%, your doctor should look for the cause. If you have conditions that cause fluid retention, a history of depression, or diabetes, your doctor should provide special attention to your

# Exhibit 5



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September 11, 2012 7:30 p.m. Webinar  
"Redefining the Role of Progesterone Therapy in ART"  
presented by Watson Pharmaceuticals and hosted by Kaylen M. Silverberg, MD

Transcribed from files produced on October 26, 2012 by Watson  
Pharmaceuticals in Response to Order for Expedited Discovery  
in Ferring Pharmaceuticals Inc. v. Watson Pharmaceuticals, Inc.  
(D.N.J. Civil Action No. 12-cv-05824-DMC-JAD)

1 retrieval, so 1 day out. And if you look at the  
2 results, no differences between the three groups.  
3 Crinone 42 percent ongoing pregnancy rate, Endometrin  
4 three times a day, 42 percent, Endometrin twice a day  
5 39 percent. You may want to ask some questions to delve  
6 into this data a little bit more in the question and  
7 answer session, but this is what I'm going to present to  
8 you so far.

9 So what do we know about these drugs? We  
10 know that vaginal progesterones come in different  
11 formulations and they all work. Efficacy is received  
12 across all platforms. But what difference is the dosing  
13 requirement. So Crinone can be given once a day, in  
14 fact it's the only FDA product that is approved once a  
15 day for progesterone, and it is approved both for  
16 supplementation and it's the only drug approved for  
17 progesterone replacement. So if you want to get any  
18 drug in luteal phase -- in first degree of transfer  
19 cycles or to down road recipients, Crinone is the only  
20 FDA approved choice. Prometrium capsules are approved  
21 for supplementation given three times a day, Endometrin  
22 inserts are also approved by the FDA as a  
23 supplementation given twice a day or three times a day,  
24 again there are differences in those data, and there's  
25 also a suggestion, if you read the package insert, for



1 Endometrin there is a black box warning showing the  
2 efficacy has not been demonstrated with -- with  
3 Endometrin for patients 35 years of age and older.

4 And what about patient centered aspects of  
5 therapy, because this is what it's all about? And we  
6 know from survey data when you compare Crinone to  
7 Prometrium vaginal capsules, 89 -- almost 90 percent of  
8 patients preferred Crinone because they thought it was  
9 easier to administer, 94 percent thought that it was  
10 more convenient to use it once a day. 75 percent  
11 thought that it was less messy. 85 plus percent thought  
12 that it was preferred. When you look at Crinone  
13 compared to Endometrin, similar findings. 94 percent of  
14 patients thought that Crinone was easier to incorporate  
15 into their daily lifestyle, probably because it's given  
16 once a day compared to three times a day for Endometrin,  
17 82 percent thought that it was more convenient, or I'm  
18 sorry, that may be 88 percent, 94 percent thought that  
19 it was more comfortable to use Crinone than the  
20 Endometrin.

21 The product information is here. We know  
22 that as far as indications, Crinone is indicated by the  
23 FDA for supplementation or replacement as part of an ART  
24 cycle, as treatment for infertile women with  
25 progesterone deficiency. Again it's the only once daily

1 FDA approved progesterone for progesterone  
2 supplementation, and it's the only FDA approved product  
3 at all for progesterone for replacement. We know that  
4 efficacy has been established for Crinone in patients  
5 under the age of 35 as well as over the age of 35.  
6 Schoolcraft's analysis of the Doody study and also our  
7 study found the exact same thing. Crinone has also been  
8 approved for use up to the 12th week in pregnancy. So  
9 as far as indication, when we're giving it for  
10 supplementation, we give it once a day. When we're  
11 giving it for replacement, frozen embryo transfer  
12 patients, donor egg recipients, we give it twice a day.  
13 Just like we raised the dose for IM in the old days.

14 Adverse effects you can see listed on the  
15 screen. We're not going to go through these. All the  
16 progestones essentially have the same adverse effects.  
17 There are really no differences.

18 So to summarize, Crinone is the only once  
19 daily FDA approved progesterone for progesterone  
20 supplementation. It's the only FDA approved  
21 progesterone at all for progesterone replacement. In  
22 clinical trials, Crinone had comparable efficacy to IM  
23 progesterone with once daily dosing in IVF, and we know  
24 that the efficacy of Crinone has been established in  
25 women age 22 all the way to age 47, including women age